8-23-99

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DATA EVALUATION RECORD

PROHEXADIONE CALCIUM
(BAS 125 08 W)

Study Type: §81-1; Acute Oral Toxicity

Work Assignment No. 1-02-25BB (MRID 44457736)

Prepared for
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U.S. Environmental Protection Agency
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Disclaimer

This Data Evaluation Record may have been altered by the Health Effects Division subsequent to signing by Dynamac Corporation personnel.

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For AK Mogby 8/25/95

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For SD Mogby 8/23/95

DATA EVALUATION RECORD

STUDY TYPE: Acute Oral Toxicity - Rat
OPPTS Number: 870.1100 OPP Guideline Number: §81-1

DP BARCODE: D246707 SUBMISSION CODE: S543930
P.C. CODE: 112600 TOX. CHEM. NO.: None

TEST MATERIAL (PURITY): Prohexadione calcium (74.9% purity)

SYNONYMS: BAS 125 08 W; calcium salt of 3-oxido-4-propionyl-5-oxo-3-cyclohexene-carboxylate

CITATION: Poelloth, C. (1996) Study on the acute oral toxicity of BAS 125 08 W in rats. BASF Aktiengesellschaft, Ludwigshafen/Rhine, Federal Republic of Germany. Laboratory Project Number 10A0242/951043. February 7, 1996. MRID 44457736. Unpublished.

SPONSOR: BASF Corporation, P.O. Box 13528, Research Triangle Park, NC.

EXECUTIVE SUMMARY: In an acute oral toxicity study (MRID 44457736), five young adult Wistar CHBB:THOM (SPF) rats/sex were given a single oral dose of prohexadione calcium (74.9% purity) at 5,000 mg/kg (limit dose). The test substance was administered at a 50% (w:v) concentration in distilled water. Animals were observed for clinical signs of toxicity and mortality for up to 14 days postdosing.

Oral LD_{50} Males = >5,000 mg/kg (observed)
Females = >5,000 mg/kg (observed)

Prohexadione calcium is classified as **TOXICITY CATEGORY IV** based on the observed LD_{50} values in both sexes.

All animals survived and appeared normal during the 14-day study. No effect on body weight was observed, and necropsy revealed no gross abnormalities.

This study is classified **acceptable (§81-1)** and satisfies the guideline requirement for an acute oral study in the rat.

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COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

I. MATERIALS AND METHODS

A. MATERIALS:

1. Test Material: Prohexadione calcium (BAS 125 08 W)
   Description: Light brown granules
   Lot/Batch #: AF 284-79
   Purity: 74.9%
   CAS #: 127277-53-6

2. Vehicle: Distilled water

3. Test animals: Species: Rat, albino
   Strain: Wistar, CHBB:THOM (SPF)
   Age: Young adult
   Weight: 180-190 g males; 175-179 g females
   Source: Dr. K. Thomae GMBH, Biberach, Federal Republic of Germany
   Acclimation period: ≥1 Week
   Diet: Kliba-Labordiaet 343, Klingetalmuehle AG Keiseraugst, Switzerland, ad libitum
   Water: Tap water, ad libitum
   Housing: One animal/cage in stainless steel wire mesh cages
   Environmental conditions:
   Temperature: 20-24 °C
   Relative humidity: 30-70%
   Air changes: Not specified
   Light: 12-Hour light/dark cycle

B. STUDY DESIGN and METHODS:

1. In-life dates: August 2-16, 1995

2. Animal assignment and treatment: Following a 16-hour fasting period, five young adult Wistar CHBB:THOM (SPF) rats/sex were given a single oral dose of prohexadione calcium at 5,000 mg/kg (limit dose) by gavage. The test substance was administered at a 50% (w:v) concentration in distilled water at a constant dosing volume of 10 mL/kg. The rats were observed for signs of toxicity and/or mortality "several times" on the day of dosing and at least once daily thereafter for up to 14 days. Body weights were recorded at 0 (prior to dosing), 7, and 13 days. At 13 days, the surviving animals were fasted for at least 16 hours, then sacrificed, necropsied, and

examined for gross pathological changes.

3. Statistics: Not applicable to this study.

II. RESULTS AND DISCUSSION:

A. Mortality: All animals survived the 14-day study.

Oral LD_{50} Males = >5,000 mg/kg (observed)
Females = >5,000 mg/kg (observed)

B. Clinical observations: No signs of toxicity were observed.

C. Body Weight: No significant treatment-related effect on body weight was observed. Overall (0-13 days), all animals gained weight, with average increases of 46% for males and 23% for females.

D. Necropsy: Necropsy after 14 days revealed no observable abnormalities.

E. Deficiencies: There were no deficiencies that affected the results of this study.